

# Overcoming the Crisis of Confidence: Risk Regulation in an Enlarged European Union

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**Overcoming the Crisis of Confidence:  
Risk Regulation in an Enlarged  
European Union**

## Colofon

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# **Overcoming the Crisis of Confidence: Risk Regulation in an Enlarged European Union**

## **Oratie**

uitgesproken bij de aanvaarding van het ambt van  
hoogleraar Europees recht aan de Universiteit Maastricht

op vrijdag 23 januari 2004

door

**Dr. E.I.L. Vos**



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Mijnheer de Rector Magnificus,  
Dames en Heren,

## 1 Crisis of Confidence

Is it still safe to eat farmed salmon?<sup>1</sup> After mad cows and dioxin chicken we are now confronted with contaminated salmon. Whom should we trust? American and Canadian scientists who, on the basis of a recent study,<sup>2</sup> claim that farmed salmon contains potentially hazardous levels of dioxins and PCBs?<sup>3</sup> Or, should we believe French,<sup>4</sup> British<sup>5</sup> and Dutch<sup>6</sup> scientists who argue that the available data does not raise any new food safety concerns?<sup>7</sup> This involves questions of how much weight we attach to the relevant scientific studies and how much confidence we have in the correctness of scientific studies and of regulatory decisions subsequently adopted.

In the past few years, public trust has been undermined by several food scandals. In particular, the BSE<sup>8</sup> crisis of 1996 led to a severe crisis of public confidence in both scientific advice and in the management of risks by the EU authorities. This crisis provided a classic illustration of uncertainty in science and of the complex and vital relationship

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1 Financial Times, 'How fish farming could feed the world', 13 January 2004.

2 R. Hites *et al.*, 'Global Assessment of Organic Contaminants in Farmed Salmon', 303 *Science* 2004, p. 226-229.

3 Polychlorinated Biphenyls.

4 <[http://www.afssa.fr/ftp/afssa/actu/communiqué\\_saumon.pdf](http://www.afssa.fr/ftp/afssa/actu/communiqué_saumon.pdf)>.

5 <<http://www.foodstandards.gov.uk/news/newsarchive/sciencestudysalmon>>.

6 <<http://www.vwa.nl>>; archives of 13 January 2004.

7 The British Food Standards Agency explains this divergence by the different approaches to setting guideline safety levels taken by, on the one hand, the US Environmental Protection Agency (EPA) and, on the other, bodies such as the US Food and Drug Administration, the World Health Organization, the Scientific Committee on Food, that advised the European Commission, and the UK Committee on Toxicity.

See <<http://www.foodstandards.gov.uk/news/newsarchive/sciencriskdioxins>>. In his speech before the European Parliament of 10 February 2004, European Commissioner for Health and Consumer Protection, D. Byrne commented that although the American study did not raise new food safety issues, the presence of the contaminants was a cause for concern, see SPEECH/04/69.

8 Bovine Spongiform Encephalopathy.

between science and society. It put the spotlight on a series of severe institutional shortcomings in EU policies on risk.<sup>9</sup> A flood of contradictory and often incomplete information amplified the fears of European citizens.

All these concerns make up part of what we may call a 'paradox of progress'. On the one hand, due to progress in science and technology, the agro-food sector must respect ever-stricter standards, quality control and monitoring procedures. On the other hand, paradoxically, over the past decade there has also been an increasing number of food-safety alerts, such as BSE, dioxin, listeria and salmonella.<sup>10</sup> Both regulators and the general public have consequently become increasingly aware of the risks that are intrinsic to the food industry. In addition, the continuous stretching of the frontiers of science in areas such as biotechnology raises anxiety among the public.<sup>11</sup> As a result, the general loss of confidence has led to a decrease in the perceived authority of science and to an erosion of the credibility and legitimacy of public decision-makers.<sup>12</sup>

According to a European survey on biotechnology, in 2002 scientists still enjoyed the trust of European citizens. Yet, the same survey shows that only half of the Europeans consulted are interested in science and many of them consider themselves to be poorly informed.<sup>13</sup> Moreover, a decline in public trust of governments and politicians can be observed. This confirms that the problem of confidence is not confined to the EU, but also pertains to national institutions. Less than 50% of the

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9 Report of the Temporary Committee of Inquiry into BSE, set up by the Parliament in July 1996, on the alleged contraventions or mal-administration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and the national courts of 7 February 1997, A4-0020/97 (Rapporteur Ortega).

10 See *The Paradox of Progress*, European Research 2002, <[http://europa.eu.int/comm/research/fp6/pdf/food\\_en.pdf](http://europa.eu.int/comm/research/fp6/pdf/food_en.pdf)>.

11 UK House of Lords, Select Committee on Science and Technology, 3rd report 1999-2000, 23 February 2000, summary, <<http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3801.htm>>; B. Wynne, (2000) 'Public Participation in 'Scientific Issues': what is the recent fuss about and how should we address it?', British Council lecture, 10 October 2000.

12 With regard to risk perception, see, *inter alia*, P. Slovic, (Ed.), *The Perception of Risk* (London, Earthscan, 2000) and N. Pidgeon, R.E. Kasperson, P. Slovic, *The Social Amplification of Risk* (Cambridge, Cambridge University Press, 2003).

13 Europeans and Biotechnology, Eurobarometer, nr. 58, second edition, March 2003, p. 28, <[http://europa.eu.int/comm/public\\_opinion/archives/ebs/ebs\\_177\\_en.pdf](http://europa.eu.int/comm/public_opinion/archives/ebs/ebs_177_en.pdf)>.



Europeans consulted have confidence in their own government and in industry in relation to biotechnology.<sup>14</sup> It is interesting to note that there is more confidence in the European Commission than in national governments.<sup>15</sup> The most recent general EU public opinion analysis shows, however, that in 2003 the confidence rating for the European Commission, the European Parliament and the Council has continued to decline.<sup>16</sup> These figures indicate that much must still be done to build public trust in the EU regulators. Clearly, the confidence problem is also a reflection of more general concerns as to the legitimacy and accountability of the EU and its law-making powers, due to the pervasiveness of EU integration in many fields.<sup>17</sup> General problems relate to the feeling that there is a lack of involvement in major decisions, a low level of understanding of how the EU functions and a weak acceptance of the system as such.<sup>18</sup>

Not only citizens, but also Member States often voice explicit distrust towards the European Union. Confidence problems are expressed in the fact that Member States are increasingly willing to ignore or to disagree with EU legislation. Thus, a trend may be observed in that Member States increasingly want to opt out of the Community's harmonisation measures in the field of health and safety and environmental protection and set higher levels of protection for their own citizens.<sup>19</sup> In addition, more

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14 *Ibid.*, p. 31-32. See also the UK Select Committee on Science and Technology, which identified, on the basis of survey data, that negative responses to science associated with Government or industry are expressed as a lack of trust, *supra* note 11.

15 It is not surprising that there is more confidence in university scientists than in scientists working for industry (with confidence surpluses of 76% and 56% respectively). Europeans and Biotechnology, *ibid.*

16 Eurobarometer 60, Autumn 2003, First results, p. 6. See

[http://europa.eu.int/comm/public\\_opinion/archives/eb/eb60/eb60\\_en.pdf](http://europa.eu.int/comm/public_opinion/archives/eb/eb60/eb60_en.pdf).

17 See for recent examples, D. Wincott and A.M. Arnall (Eds.), *Accountability and Legitimacy in the European Union* (Oxford, Oxford University Press, 2002) and K. Lenaerts and M. Desomer, 'New Models of Constitution-making in the Europe: the Quest for Legitimacy', 39(6) *Common Market Law Review* 2002, p. 1217-1253.

18 See E. Best, 'Transparency and European Governance: Clearly not a simple matter', in: V. Deckmyn (Ed.), *Increasing Transparency in the European Union?* (Maastricht, EIPA, 2002), p. 93.

19 See for an analysis, N. de Sadeleer, 'Procedures for Derogations from the Principle of Approximation of Laws under Article 95 EC', 40(4) *Common Market Law Review* 2003, p. 889-915. See also J. Zander, 'The Green Guarantee in the EC Treaty: Two recent cases', 16(1) *Journal of Environmental Law* 2004, p. 65-79.

and more often Member States are hesitant to adhere to Community norms. Let me briefly illustrate this with two concrete examples.

First, I would like to recall the refusal of France to implement the Commission's decision of 1999 to lift the embargo on the export of British beef.<sup>20</sup> This decision had been based on the positive opinion of the Community's Scientific Steering Committee regarding the safety of British beef. In order to justify its refusal, France invoked the scientific opinion of its own food safety agency, *l'Agence Française Sécurité Sanitaire des Aliments*.<sup>21</sup> This agency held that serious doubts still remained as to the risks presented by British beef. The European Court of Justice, however, elegantly avoided taking this argument into account on procedural grounds. It condemned such behaviour by France and forced France to comply with the Commission's decision and hence, lift the ban. At the same time, however, it underlined the necessity for a Europeanisation of beef traceability systems in the absence of which France, in some cases, was allowed to block British beef from entering its market in order to protect human health.<sup>22</sup>

Second, Austria, Luxembourg and Italy have openly refused to comply with Community legislation on genetically modified organisms (GMOs) and novel food. Austria and Luxembourg have denied access of GM maize products onto their markets, notwithstanding the fact that the marketing of these products had been authorised by the Commission.<sup>23</sup>

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20 Commission Decision 1999/514/EC setting the date on which dispatch from the United Kingdom of bovine products under the date-based export scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC (notified under document number C(1999) 2500), (1999) OJ L 195/42.

21 Loi 98-535 du 1er juillet 1998 relative à la veille sanitaire et la surveillance des produits destinés à l'homme. Website: <<http://www.afssa.fr/>>.

22 Case C-1/00, *Commission v. France*, [2001] ECR I-9989.

23 In spite of many objections raised by several Member States, the Commission had approved four GM maize products and one swede rape product. See Commission Decision 97/98/EC concerning herbicide-tolerant GM maize produced by Ciba-Geigy (now Novartis), (1997) OJ L 31/69; Commission Decision 98/292/EC concerning grains of GM maize produced by Novartis, (1998) OJ L 131/28; Commission Decision 98/293/EC concerning seeds and grains of GM maize produced by AgrEvo, (1998) OJ L 131/30; Commission Decision 98/294/EC concerning herbicide-tolerant GM maize produced by Monsanto, (1998) OJ L 131/32 and Commission Decision 98/291/EC concerning GM spring swede rapes produced by AgrEvo, (1998) OJ L 131/26.

Italy used the safeguard clause of the Novel Food Regulation to suspend the trade and use of all products derived from GM maize.<sup>24</sup> In a preliminary ruling, the European Court of Justice recently recognised the power of Member States to adopt diverging, protective measures, on the basis of the precautionary principle, if such measures are necessary to protect human health and safety.<sup>25</sup>

This lack of trust underlies some of the most pressing tensions in the governance of the internal market of the EU, namely: the increasing divergence between scientific opinion and public opinion, the continuously conflicting scientific opinions of Community, national and international bodies and, closely linked to this, the increasingly differing positions of Member State and Community authorities. These tensions indicate that the often ad-hoc methods and procedures, by means of which the EU has traditionally dealt with socially sensitive and scientifically complex issues, are inadequate, and that the European integration process is endangered. This calls for regulatory reform. The central question is how to improve the credibility of the EU regulatory structures that govern mad cows, dioxin chicken and contaminated salmon?

## 2 The Need for an Overarching Approach to Risk Regulation

Before examining this question, let me briefly explain the complexities of risk regulation. According to the German sociologist Ulrich Beck, modern society is no longer preoccupied with the distribution of wealth, and the division of society along classes, but is increasingly concerned with the distribution of risk. Modern society has thus transformed into a 'risk society'.<sup>26</sup> In pursuing its objectives of creating an internal market on which products freely circulate, as well as of protecting human health and safety, the EU is now also increasingly faced with the concerns of today's risk society. The regulatory activities of the 'risk

24 The Italian Decree of the President of the Council of Ministers of 4 August 2000 on the precautionary suspension of the trade in and use of certain transgenic products within national territory under Article 12 of Regulation No 258/97 (GURI No 184 of 8 August 2000, p. 9).

25 Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others*, not yet reported, para. 114. In those cases Member States must nevertheless first carry out a risk assessment 'which is as complete as possible given the particular circumstances of the case'.

26 U. Beck, *Risikogesellschaft, Auf dem Weg in eine andere Moderne* (Frankfurt a.M., Suhrkamp Verlag, 1986).

society' involve risk assessment, risk management and risk communication. Risk assessment refers to the evaluation of the risks associated with specific substances or products. Risk management concerns the regulatory decisions on what to do about these risks. Risk communication refers to the process of informing the public of both scientific findings and regulatory decisions.

In many fields, it is currently the EU that has to determine whether a product's attendant risks are judged to be 'acceptable'.<sup>27</sup> This requires the EU to rank norms or values and to balance competing factors such as safety and economic competitiveness. Yet, such decisions are often presented by decision-makers as stemming only from 'sound science'. This strong reliance on science may be argued to result in an increasing scientification of politics. Where the uncertainty of scientific knowledge is increasingly recognised, this leads, paradoxically, to the politicisation of science.<sup>28</sup> In the face of scientific uncertainty, scientists cannot and will not limit themselves to addressing 'purely scientific issues'.<sup>29</sup> Not surprisingly, voices are heard calling for participation of the stakeholders and/or laypersons in the formulation of scientific opinions.<sup>30</sup> Also, the proper application of and compliance with EU legislation are essential to create a climate of trust. Both Member States and citizens should be able to rely on the fact that the law will be enforced fairly.<sup>31</sup>

This will be even more important in the post-enlargement situation. Food safety, for example, is of major concern for the upcoming enlargement. Many of the new EU countries will not have complied with the EU food safety requirements by the time they join the EU on 1 May 2004.<sup>32</sup>

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27 See W. Lowrance, *Of Acceptable Risk: Science and the Determination of Safety* (Los Altos, CA, William Kaufmann Inc., 1976).

28 See P. Weingart, 'Scientific expertise and political accountability: paradoxes of science in politics', 26(3) *Science and Public Policy* 1999, p. 151-161.

29 S. Jasanoff, *The Fifth Branch: Science Advisors as Policy Makers* (Cambridge MA, Harvard University Press, 1990), p. 249.

30 See e.g. B. Wynne, 'May the Sheep Safely Graze: a Reflexive View of the Expert-Lay Knowledge Divide', in: S. Lash, B. Szerszynski and B. Wynne (Eds.), *Risk, Environment and Modernity: Towards a New Ecology* (London, Sage, 1996), 44-83.

31 See, *inter alia*, Commission Communication Better Monitoring of the Application of Community Law, COM(2002) 725 final.

32 D. Byrne, European Commissioner for Health and Consumer Protection, *Enlargement, Food Imports and Rural Development*, speech before the EEP Seminar in Brussels, 10 December 2003, SPEECH/03/606.

Clearly, however, the level of food safety can and should not be compromised. Under the Accession Treaty, the Commission has the power to take appropriate measures should these countries fail to implement Community obligations and thus, put the proper functioning of the internal market at risk.<sup>33</sup> Recently, Commissioner Byrne nevertheless stressed that 'it is in everyone's interest to avoid the use of such measures'.<sup>34</sup>

It will also be very likely that the current Member States will resort to safeguard clauses laid down in specific directives or to the opt-out procedure laid down in the Treaty.<sup>35</sup> Safeguard clauses enable Member States to temporarily block the free movement of foodstuffs originating in other Member States if they endanger human health or safety. The opt-out procedure allows Member States to deviate, under certain conditions, from the Community's harmonisation measures if this is necessary to protect human health.<sup>36</sup> This could lead to a Europe of two, or even more, speeds, as is actually favoured by the President of the Commission Romano Prodi, but very much opposed by the Prime Minister of Ireland who now holds the EU Presidency.<sup>37</sup> Does this mean

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33 Article 38 of the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, (2003) OJ L236/33.

34 D. Byrne, *supra* note 32. In the newsletter *Consumer Voice* of DG SANCO of April 2004, however, the Commission re-assures that 'EU newcomers comply with food safety standards'. Nevertheless it is doubtful whether this will be the case in practice since many new Member States are likely to have problems when they apply the rules. See A. Surdej, 'Enlarging the EU Food Safety Regime: Selected Problems in Adjusting the Polish Food Safety Regime to EU Food Safety Requirements', in: G. Majone (ed.) *Risk Regulation in the European Union: Between Enlargement and Internationalisation* (Florence, EUI/RSCAS, 2003), p. 188.

35 Article 95 (4-9) EC.

36 See J. Scott and E. Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO', in Chr. Joerges and R. Dehousse, *Good Governance in Europe's Integrated Market* (Oxford, Oxford University Press, 2002), p. 267-273 and N. de Sadeleer, *supra* note 19.

37 See Press Release from the Irish Presidency of 4 January 2004, 'Ahern says "the best way that Europe operates is moving together"', <[http://www.eu2004.ie/templates/news.asp?sNavlocator=66&list\\_id=8](http://www.eu2004.ie/templates/news.asp?sNavlocator=66&list_id=8)>.

that the enlarged European Union will grow into a 'European Union' with different layers of measures applicable to various Member States?<sup>38</sup>

Ladies and gentlemen, it is clear that these matters need to be addressed by means of a comprehensive and integrated approach to food safety. This does not mean that the EU should be exclusively responsible for all aspects of food safety. However, it demands that all aspects of food safety are addressed at the EU level, requiring an appropriate concept of shared responsibility.<sup>39</sup> If we do not want the Lisbon objective of becoming the most competitive and dynamic knowledge-based economy by 2010 to remain an 'EU-topia', it is clear that many problems are still to be tackled in this area.

These problems can roughly be divided into institutional and substantive issues of a more general nature and issues, which relate to risk regulation more specifically. I would like to share with you the most important ones.

On an institutional level, questions arise as to competence and multi-level governance. For example, which authority should regulate: the European Parliament and the Council, the Commission possibly together with comitology committees, or a separate European agency? This question is closely linked with the question of separation and delegation of powers. What should be the institutional arrangements (such as the composition of committees or agencies) in view of the enlargement? Moreover, questions concerning legitimacy and good governance exist, while the quality of EU legislation, as well as its implementation, compliance and enforcement, are also problematic. Recently it appeared that countries, including The Netherlands, have an ever-increasing backlog of EU directives awaiting implementation.<sup>40</sup>

38 See E. Vos, 'Differentiation, Harmonisation and Governance', in B. de Witte, D. Hanf en E. Vos (Eds.), *The Many Faces of Differentiation in EU Law* (Antwerp, Intersentia Publishing, 2001), p. 177.

39 See the Commission in its White Paper on Food Safety, COM(1999) 719 final.

40 See Press Release from DG Internal Market of 12 January 2004, 'Internal Market: big disparities between Member States in implementing and applying rules', IP/04/33. See also the Internal Market Scoreboard Nr. 12 of 5 May 2003, <[http://europa.eu.int/comm/internal\\_market/en/update/score/score12/score12-text\\_en.pdf](http://europa.eu.int/comm/internal_market/en/update/score/score12/score12-text_en.pdf)> and the Commission Report on the Implementation of the Internal Market Strategy (2003-2006), COM(2004) 22 final.

On a substantive level, difficulties arise with regard to the inter-relationship and compatibility of EU policies. Food safety regulation touches upon, for instance, health and safety protection, internal market, agriculture and external relations, and in particular WTO law. How can both the free movement of goods and human health protection be ensured? How is compliance with international obligations guaranteed? An excellent example of this difficulty is, of course, the dispute between the US and the EU on genetically modified organisms.<sup>41</sup>

Questions that relate more specifically to risk regulation are the manner in which science is developed and how the Community should deal with scientific uncertainty. In addition it is asked how it should define what risks are acceptable and how such risks should be communicated. Here, the application of the precautionary principle is of paramount importance. On the basis of this principle, regulators may take protective measures although scientific evidence on the risk or on the causal relation between the risk and the damage is lacking.<sup>42</sup> Closely linked hereto, and of additional importance, are issues relating to the incorporation of public concerns and communication of the results in risk assessment and risk management and the role of the institutions involved therein. Other problems relate to the question of whether risk assessment and risk management should be separated.

Thus, in order to restore public confidence in risk regulation and enhance legitimacy, several avenues may be explored. These avenues all relate to the 'new governance thinking'.<sup>43</sup> This thinking is expressed, *inter alia*, in the perspectives on multi-level networks, the role of independent agencies and deliberative democracy. Key elements of governance or better, good governance, are transparency, public participation and accountability. Not surprisingly these elements form a prominent part of the European Commission's White Paper on European

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41 Ongoing disputes before the Dispute Settlement Body of the WTO initiated by the US, Canada and Argentina: WT/DS291/23, WT/DS292/17 and WT/DS293/17.

42 See for an overview of the legal debate on the precautionary principle: M. Faure and E. Vos (Eds.), *Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen* (Den Haag, Gezondheidsraad, 2003). Available at <<http://www.gr.nl/pdf.php?ID=723>>.

43 See J. Scott and D. Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union', 8(1) *European Law Journal* 2002, p. 1-18.

Governance of July 2001.<sup>44</sup> The use of independent agencies is generally advocated to generate greater regulatory credibility as it may ensure more transparency and accountability.<sup>45</sup>

I have tried to show that regulating food safety and, more generally, risk, clearly is an extremely complicated and interdisciplinary undertaking. It provides us, fortunate researchers, with a challenging and exciting research agenda. Several of these issues will therefore form part of the research and teaching activities I would like to pursue in the coming years. You will understand that today I will not discuss all these elements. By way of example, I will explore some of the initiatives by means of which the European institutions, in particular the Commission, have attempted to overcome the crisis of confidence and more generally the legitimacy problem: namely, by putting in place principles of good governance.

### 3 Enhancing Credibility by Means of Principles of Good Governance

In a speech before the European Parliament in 2000, Romani Prodi observed on the one hand, the success of European integration and the internal market, enabling the EU to emerge as a world economic power capable of meeting the challenges of globalisation and on the other, the loss of faith of Europe's citizens in the European institutions.<sup>46</sup> The European Commission has therefore looked for a new balance between action by the Commission, the other Community institutions, the Member States and civil society.<sup>47</sup> In its White Paper on European Governance, the Commission recognises that 'people increasingly distrust institutions and politics or are simply not interested in them', and that this problem 'is particularly acute at the EU level'. It believes that 'many people are losing confidence in a poorly understood and complex system'.<sup>48</sup>

44 White Paper on European Governance, COM(2001) 428 final.

45 See G. Majone, 'The Credibility Crisis of Community Regulation', 38(2) *Journal of Common Market Studies* 2000, p. 273-302.

46 R. Prodi, President of the European Commission 2000-2005, *Shaping the New Europe*, speech before the European Parliament, 15 February 2000, Strasbourg, SPEECH/00/41.

47 Commission Communication, Strategic objectives 2000-2005 'Shaping the New Europe', COM (2000) 154 final, p. 5.

48 White Paper on European Governance, *supra* note 44, p. 3.



The Commission explains the dissatisfaction with EU policies and the functioning of the institutions, inter alia, by the perceived inability of the EU to act effectively in situations of food scares. It complains that part of the distrust is also due to the fact that Member States often blame 'Brussels' for unpopular decisions, although these decisions have been taken in agreement with, or even upon request of, these Member States. It tells us that 'the EU is often seen as remote and at the same time too intrusive'.<sup>49</sup> The Commission recognises that people should be given a greater say in the way Europe is run. It therefore seeks new means to improve governance and proposes to open up the policy-making process to get more people and organisations involved in shaping and delivering EU policy. It promotes five principles as principles of good governance: openness, participation, accountability, effectiveness and coherence. These principles are, in its view, 'important for establishing more democratic governance'.<sup>50</sup>

Allow me to briefly draw upon some of the initiatives the institutions have undertaken with regard to two of these principles that are generally considered to be essential to generate public trust in risk regulation: openness and participation.<sup>51</sup>

### *Openness and Transparency*

The BSE crisis has taught us that openness and transparency in both decision-making and the formulation of scientific advice is of paramount importance. This was not only stressed in 1997 by the European Parliament Inquiry Committee on BSE,<sup>52</sup> but was also more recently underlined by the British Inquiry Committee on BSE in the UK.<sup>53</sup> Drawing lessons from the UK BSE crisis, the latter Committee tells us that openness also requires recognition of uncertainty, where it exists. Although regulators generally fear that this kind of openness would create an

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49 *Ibid.*, p. 5.

50 *Ibid.*, p. 10.

51 See P. Harremoës et al. (Eds.), *The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings* (London, Earthscan, 2002), p. 216-217.

52 Report of the Temporary Committee of Inquiry into BSE, *supra* note 9.

53 The so called Phillips Report, published as a Return to an Order of the Honourable the House of Commons dated October 2000 for the Report, evidence and supporting papers of the Inquiry into the emergence and identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (vCJD) and the action taken in response to it up to 20 March 1996, <<http://www.bseinquiry.gov.uk/report/index.htm>>.

irrational reaction by the public and increase fears and distrust, it is suggested that the public should be trusted to respond rationally to openness. The Committee recommends that scientific investigation of risk should be open and transparent, and that the advice and the reasoning of advisory committees should be made public.<sup>54</sup>

Following the 1996 BSE crisis the Community institutions were indeed quick to improve transparency of both decision-making and science in the hope of restoring the citizens' confidence in European regulation.<sup>55</sup> The Commission first carried out a radical restructuring of all its departments by transferring the responsibility for decision-making involving human health and safety to the Directorate General Health and Consumer Protection. Subsequently, it proclaimed that it would develop a new approach to food safety based, *inter alia*, on greater transparency and information throughout the decision-making process and inspection.<sup>56</sup>

At the same time, the institutions have facilitated access to their documents, in all policy fields.<sup>57</sup> Transparency has, since many years, ranked highly on the political agenda. The Treaty of Amsterdam introduced a right of access to documents of the Council, the Commission and the European Parliament<sup>58</sup> and required transparency in decision-making.<sup>59</sup> Unsurprisingly, the European Convention has also put great weight on transparency and has further developed it. Consequently, '[i]n order to promote good governance and ensure the participation of civil society', the Draft Constitution explicitly requires that 'the Union Institutions, bodies and agencies shall conduct their work as openly as possible'.<sup>60</sup>

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54 *Ibid.*

55 See for an analysis of the new approach to food safety, E. Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis', 23(3) *Journal of Consumer Policy* 2000, p. 227-255. See more recently, D. Chalmers, "'Food for Thought", Reconciling European Risks and Traditional Ways of Life', 66(4) *Modern Law Review* 2003, p. 533-562.

56 Green Paper on the General Principles of Food Law in the European Union, COM (1997) 176 final.

57 D. Curtin, "'Citizens' fundamental right of access to EU information: An evolving digital passepartout?", 37(1) *Common Market Law Review* 2000, p. 7-41.

58 Article 255 EC.

59 Article 1 EU.

60 Article 49 of the Draft Treaty establishing a Constitution for Europe, CONV 850/03.

Notably, the institutions have paid particular attention to ensuring more transparency in the way scientific advice is constructed. The New Approach to Food Safety, for instance, introduced in 1997 - in addition to the principles of excellence and independence - the principle of transparency, to govern the then-existing scientific committees.<sup>61</sup> As these measures proved still insufficient to restore public confidence,<sup>62</sup> a more conceptual approach to food safety was adopted in 1999, called 'From Farm to Table' or 'From the Farm to the Fork'.<sup>63</sup> In 2002, based on this new policy, a Food Regulation was adopted with a new framework for food-stuffs.<sup>64</sup> The new food law establishes the requirement, as part of the legislative framework, that risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data. An important development, with a view to fulfilling this aim, has been the establishment of the European Food Safety Authority (EFSA).<sup>65</sup>

This agency has been central in the Commission's strategy to restore consumer confidence.<sup>66</sup> By means of this agency, transparency is promoted whilst at the same time the independence and quality of scientific advice is also enhanced. Significantly, the EFSA must immediately make its findings public concerning risks to European consumers.<sup>67</sup> Transparency, with respect to this issue, also includes the ease of access

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61 Green Paper on Consumer Health and Food Safety, COM (1997) 183 final.

62 Subsequent scares of food safety (in particular concerning dioxin contamination) increased public awareness and undermined even further the confidence of consumers in the capacity of the food industry (in its broadest sense) and the public authorities to ensure that their food is safe even, as Commissioner Byrne admitted in 1999. D. Byrne, Commissioner DG Health and Consumer Protection, Food Safety in Europe in his speech for the Arthur Cox Conference on Food Law, 5 November 1999, Dublin, SPEECH/99/156.

63 White Paper on Food Safety, COM (1999) 719 final.

64 Regulation (EC) No 178/2002 of 28 January 2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, (2002) OJ L 31/1.

65 Article 22 of Regulation (EC) No 178/2002, *supra* note 64.

66 See Commissioner D. Byrne at <[http://europa.eu.int/comm/commissioners/byrne/key-issues\\_en.htm#EFA](http://europa.eu.int/comm/commissioners/byrne/key-issues_en.htm#EFA)>.

67 Article 40 of Regulation (EC) No 178/2002, *supra* note 64.

to information on the activities of the EFSA and its committees.<sup>68</sup> Thus, the EFSA is required to make public: the agendas of the meetings; the list of members; the opinions of the scientific committees<sup>69</sup> (including minority opinions); and its annual reports. In addition, it must publish the annual declarations of interest of all persons involved in the activities of the EFSA (the members of the Management Board, the members of the Advisory Forum, the Executive Director, the members of the Scientific Committee and the Scientific Panels) indicating any direct or indirect interests that could be considered harmful to their independence.<sup>70</sup> In this, much use is made of the Internet, which, of course, is an important element in achieving more open and public risk regulation.<sup>71</sup>

### *Participation*

Openness is a precondition for participation and accountability. Participation in both decision-making and science as a means to regain trust is promoted in several studies and documents.<sup>72</sup> An important study drawing on 14 case-studies, among which BSE, benzene, hormones and asbestos, reveals that involving a wide range of stakeholders, and taking account of their values and interests at the earliest stage of regulatory appraisal and choice of technological and social options, brings several benefits. First, this would augment the information available for policy-making. Second, this may also improve public trust in society's capacity to control hazards, without necessarily stifling innovation or compromising science. Moreover the study suggests that it may also make better science.<sup>73</sup> Opening up the traditionally closed circles of

68 Subsequently laid down in Commission Decision 97/579/EC, (1997) OJ L 237/18. Commission Decision 97/404/EC setting up a Scientific Steering Committee, (1997) OJ L 169/85.

69 The existing scientific committees in the food sector have now been absorbed into the EFSA.

70 Articles 37 and 38 of Regulation (EC) No 178/2002, *supra* note 64.

71 Website: <<http://www.efsa.eu.int>>.

72 See, *inter alia*, Report of the Working Group 'Democratising expertise and establishing scientific reference systems' (Group 1b), (rapporteur Liberatoro), European Commission, 2001, <[http://europa.eu.int/comm/governance/areas/group2/report\\_en.pdf](http://europa.eu.int/comm/governance/areas/group2/report_en.pdf)> and the Conclusions of the Conference 'Science and Governance in a Knowledge Society: the Challenge for Europe', organised by DG Joint Research Centre and DG Research, Brussels, 16-17 October 2000, p. 2, <[http://europa.eu.int/comm/governance/areas/group2/contribution\\_en.pdf](http://europa.eu.int/comm/governance/areas/group2/contribution_en.pdf)>.

73 P. Harremoës *et al.* (Eds.), *supra* note 51, p. 217.

science, by allowing interested parties to participate is, nevertheless, still quite revolutionary, even in national contexts.<sup>74</sup>

Also according to the Commission 'improved participation is likely to create more confidence in the end result and in the institutions which deliver policies'.<sup>75</sup> To this end, it has adopted a general strategy that envisages increased and more active dialogue with civil society.<sup>76</sup> In December 2002, it adopted a set of minimum standards for its consultation processes of external parties.<sup>77</sup> In addition, the Commission emphasises, in its Action Plan on Science and Society,<sup>78</sup> the need for a dialogue involving close co-operation between a wide range of stakeholders in science policies. Such stakeholders should come from research organisations, public authorities, media, citizens, civil society and enterprises. The Commission recognises that the input of the public in policy debates may disclose relevant knowledge, values or questions, which scientists have neglected. The Commission points, in this context, to innovative institutional participatory arrangements undertaken in the national contexts, such as consensus conferences, citizens' juries, national and regional consultations, on-line fora and participative foresight programmes.<sup>79</sup>

Several steps have already been taken to involve interested parties in the activities of the scientific advisors to the Commission. Interested parties may, for example, comment on various opinions of the European Food Safety Authority and other scientific committees. Furthermore in accordance with its mandate,<sup>80</sup> the EFSA has, very recently, agreed to

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74 R. Bal, W. Bijker en R. Hendriks, *Paradox van Wetenschappelijk Gezag: Over de Maatschappelijke Invloed van Adviezen van de Gezondheidsraad, 1985 - 2001* (Den Haag, Gezondheidsraad, 2002), p. 312.

75 White Paper on European Governance, *supra* note 44, p. 7. See also the Report of the Working Group 'Democratising expertise and establishing scientific reference systems', *supra* note 72.

76 White Paper on European Governance, *ibid*, p. 16.

77 Commission Communication, 'Towards a reinforced culture of consultation and dialogue - General Principles and Minimum Standards for consultation of interested parties by the Commission', COM (2002) 704 final.

78 European Commission, Science and Society Action Plan (Brussels, 2002), p. 14, available at  
<[http://europa.eu.int/comm/research/science-society/pdf/ss\\_ap\\_en.pdf](http://europa.eu.int/comm/research/science-society/pdf/ss_ap_en.pdf)>.

79 *Ibid*.

80 Article 42 of Regulation (EC) No 178/2002, *supra* note 64.

open up its work further to public scrutiny. This will entail, *inter alia*, that the Authority will allow consumers and other stakeholders to be involved in its work, by means of the creation of a stakeholder forum, and explore the possibility of having public hearings on significant scientific issues.<sup>81</sup> Importantly, participation of interested parties is also recognised by the very composition of its Management Board including four members with a background in organisations representing consumers and other interests in the food industry.<sup>82</sup> In addition, the EFSA is required to promote the networking of organisations operating in the same field as the EFSA itself in order to facilitate a scientific cooperation framework.<sup>83</sup>

The Commission also encourages the setting-up of informal networks, bringing together European decision-makers, academics, experts and stakeholders, to promote dialogue and interaction.<sup>84</sup> Furthermore, it has become more active in launching various wider consultations announcing its policy initiatives in various fields. It makes more use of green and white papers, whilst it also uses seemingly new instruments like reflection papers and discussion papers.<sup>85</sup> In this context it is interesting to observe that the Commission has set up an opportunity for on-line consultation, 'Your Voice in Europe'.<sup>86</sup> Within this framework, the Commission has launched several consultation procedures relating to

81 EFSA Press Release of 3 December 2003, 'EFSA plans greater public involvement in its work',

<[http://www.efsa.eu.int/pdf/pressrel\\_mbo11\\_final\\_en.pdf](http://www.efsa.eu.int/pdf/pressrel_mbo11_final_en.pdf)>.

82 Article 25 of Regulation (EC) No 178/2002, *supra* note 64.

83 Article 36 of Regulation (EC) No 178/2002, *ibid*.

84 In its Science and Society Action Plan, for example, the Commission explicitly mentions the TRUSTNET project which aims at analysing the factors that influence the credibility, effectiveness and legitimacy of the scientific and regulatory framework for hazardous activities, as well as developing more coherent, comprehensive and equitable approaches for assessing and managing risks. See Science and Society Action Plan, *supra* note 78, p. 14.

85 With these new expressions, the Commission seemingly wants to suggest that these papers are truly meant for discussion. In contrast to the Green and White Papers, these documents are not official COM documents. See for an example of a discussion paper: Directorate General Health and Consumer Protection (SANCO D4), 'Discussion Paper on the Implementation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients', July 2002, <[http://europa.eu.int/comm/food/fs/novel\\_food/discussion\\_en.pdf](http://europa.eu.int/comm/food/fs/novel_food/discussion_en.pdf)>.

86 <[http://europa.eu.int/yourvoice/index\\_en.htm](http://europa.eu.int/yourvoice/index_en.htm)>.

food safety.<sup>87</sup> Interested parties have, for example, been able to comment on the implementation and working of the Novel Food Regulation.<sup>88</sup> Other examples of public consultation are evident with respect to the White paper on European Governance itself<sup>89</sup> and, of course, also the European Convention in the process of designing the draft Constitution.

That the EU is serious about the involvement of citizens is clear from the insertion of the principle of participatory democracy in the draft Constitution.<sup>90</sup> This principle requires the institutions to give citizens and representative associations the opportunity to make known and publicly exchange their views on all areas of Union action. Moreover, it emphasises the need for regular consultations with concerned parties and frequent, transparent dialogue with representative associations and civil society.<sup>91</sup>

#### 4 Challenges for an Enlarged European Union

All these initiatives are, of course, laudable as they certainly contribute to more transparent and democratic risk regulation, and to restoring public trust and legitimacy in the EU. So far so good. These initiatives show however that there is not yet an overarching theoretical approach to openness, transparency and participation, and to risk governance in general. Allow me to advance some critical remarks and remaining challenges.

It seems that the EU institutions and, in particular the Commission, favour what has been called a 'mutual trust paradigm of risk governance'. This approach is characterised by a broad involvement of the stakeholders in the risk assessment and management process as well as in the justification of the hazardous activities.<sup>92</sup> It entails that science is

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87 <[http://europa.eu.int/comm/food/consultations/index\\_en.htm](http://europa.eu.int/comm/food/consultations/index_en.htm)>.

88 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, (1997) OJ L 43/1. See the Discussion Paper, *supra* note 85.

89 See e.g. COM(2002) 705, Report from the Commission on European Governance.

90 Article 45 of the Draft Constitution.

91 Article 46 of the Draft Constitution.

92 TRUSTNET, Work Program 1997-1999 - Opening a new perspective on Risk Governance, <<http://www.trustnetgovernance.com>>.

no longer presented to the public as an exclusive determining factor in the decision making process. Expertise becomes pluralistic and available to all parties involved. At the same time however the Community institutions stress the importance of resorting to sound science. For example, the EFSA is required to deliver the 'best possible scientific opinions'.<sup>93</sup> This seems difficult to reconcile with a broad interpretation of openness.

Access to documents still seems to be problematic in view of the many exceptions to the right to access.<sup>94</sup> Although the draft Constitution reinforces the right of access to documents by improving the wording of the provision laying down this right,<sup>95</sup> several issues, such as the precise legal nature of the right of access to documents, remain unclear.

In contrast to the American 'sunshine' committees,<sup>96</sup> the meetings of the EU scientific committees (and the comitology committees) are not open to the general public. Only the Management Board of the EFSA holds, as a general rule,<sup>97</sup> its meetings in public and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.<sup>98</sup>

This illustrates that it is not clear what openness and transparency actually mean in the European Union context. Do we also need to open up meetings of the scientific experts? This may raise new dilemmas as it may lead to endless discussions of viewpoints and further politicisation of science. As we have seen in the BSE crisis, scientists may, in politically sensitive cases, be put under strong political pressure.<sup>99</sup> Experts in social studies of science thus point to the danger that completely opening up the procedure of formulating scientific advice may be counterproductive. In this way, too much pressure would be exerted by the

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93 Article 23 of Regulation (EC) No. 178/2002, *supra* note 64.

94 See D. Curtin, *supra* note 57.

95 Article 49 (3) of the Draft Constitution, *supra* note 60.

96 See the US Freedom of Information Act ('FOIA'), 5 U.S.C. § 552, The Federal Advisory Committee Act (FACA), 5 U.S.C. app. II and the Government in the Sunshine Act, codified primarily at 5 U.S.C. section 552b.

97 Unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda: Article 38(2) of Regulation (EC) No. 178/2002, *supra* note 64.

98 *Ibid.*

99 See Report of the Temporary Committee of Inquiry into BSE, *supra* note 9, p. 10.



interested parties creating the risk of paralysing the process.<sup>100</sup> On the other hand, however, leaving the construction of sound science to only certified experts may lead again to the technocratic approach we want to avoid.<sup>101</sup>

Furthermore, queries remain as to what form of participation should be required. An OECD study reveals that active participation is still rare within the OECD countries.<sup>102</sup> Will this be any easier at the European level?<sup>103</sup> Active participation raises problematic practical issues, such as, who should participate (stakeholders, civil society and/or the general public), how those participating should be defined and what representativeness they should have. In fact, today the Commission's initiatives involve mostly broad consultation processes. With regard to more active participation, the Commission favours innovative institutional procedures such as consensus conferences and citizen's juries. Consensus conferences are a form of dialogue between lay people and scientists. Contrary to the name, they usually spark a debate between experts and citizens on contentious or contested questions. Based on the exchange between the experts, the citizens are supposed to form a consensus opinion. The question remains as to how effective such participatory arrangements are at the national level and, thus, can be at the European level. Social scientific research reveals various challenges associated with participatory procedures, such as consensus conference and citizen juries.<sup>104</sup> Interdisciplinary research on this topic seems therefore needed.

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100 See e.g. R. Bal, W. Bijker en R. Hendriks, *supra* note 74, p. 315.

101 *Ibid.*

102 See E. Best, *supra* note 18, p. 113. See OECD, *Citizens as Partners. Information, Consultation and Public Participation in Policy-making* (Paris, 2001).

103 See E. Best, *supra* note 18, p. 113.

104 See e.g., O. Renn, T. Webler, and P. Wiedemann, *Fairness and competence in citizen participation. Evaluation models for environmental discourse* (London, Kluwer Academic Publishers 1995); R. Löfstedt, 'The Role of Trust in the North Blackforest; an evaluation of a citizen panel project, 10 *Risk Health Safe Environment*, 1999, p. 10-30; B. Kasemir, J. Jäger, C. Jaeger, and M.T. Gardner, *Public Participation in Sustainability Science* (Cambridge, Cambridge University Press, 2003); M.B.A. van Asselt and N. Rijkens-Klomp, 'Look in the Mirror: Reflection on participation in Integrated Assessment from a methodological perspective', 12 *Global Environmental Change* 2002, 107-180; M. van de Kerkhof, *Debating climate change. A study on stakeholder participation in an integrated assessment of long-term climate policy in the Netherlands*, forthcoming.

The Commission strongly emphasises the need for extensive consultations and dialogue, as does the principle of participatory democracy in the draft Constitution. However it may be asked what a true, and most importantly successful, dialogue with the citizens should look like. I really wonder whether many of you, present here today, will have been aware that during the whole year of 2001 there was a public debate on biotechnology and food in The Netherlands.<sup>105</sup> It is doubtful that there will be any greater awareness at the EU level. Moreover, it is unsure whether such dialogue will be in any way effective for citizens of the acceding countries who have a completely different regulatory culture. Increased consultation and deliberation risk becoming 'empty proceduralism'. In many cases, minority interests are seldom aligned with each other and often, only the dominant interests are recognised. In those cases, deliberation is likely to become a hollow and lengthy procedure in which the participation of stakeholders is merely used as a justification rather than allowing for a genuine involvement in the decision-making process.<sup>106</sup> For example, according to the UK BSE Inquiry Committee, one of the major administrative weaknesses in the UK BSE affair was the lengthy consultation process used before any decision was adopted. These issues should therefore be carefully considered in the design of consultation procedures. In addition, one may wonder how the principle of participatory democracy, as laid down in the draft Constitution, will relate to the principle of representative democracy.

Without doubt, the EFSA will have a crucial role to play in restoring the trust of both citizens and regulators. It remains to be seen whether it will succeed. The tasks of the EFSA are limited to risk assessment, communication and the setting up of networks. Here it is important to observe that, in cases of diverging scientific opinions, the Authority is obliged to co-operate with the national bodies, to either resolve the conflict or to present a joint document clarifying the differences of opinion.<sup>107</sup> In situations where different methodologies or opposing data are used, however, such a joint document could be used to undermine the credibility of the other. Such a document could therefore highlight internal crises of sciences and provoke crises of confidence in scientific

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<sup>105</sup> See <<http://www.minlnv.nl/thema/biotech/publiek/inftbpoo.htm>>. The archives can be found at

<<http://www.minlnv.nl/thema/biotech/archtb200101a.htm>>.

<sup>106</sup> D. Chalmers, *supra* note 55, p. 552.

<sup>107</sup> Article 30 (4) of Regulation (EC) No 178/2002, *supra* note 64.

expectations, and, at the same time, promote beliefs in a zero-risk world. This, in turn, could affect confidence in the analytical rigour of the EFSA.<sup>108</sup> The BSE crisis has furthermore shown that the communication of risks to the public and the effective crisis management by the authorities are essential to generate confidence. Much of the success and credibility of the Authority will therefore also depend on the role it will play in this context as well as the way in which it will involve the stakeholders and the regulatory authorities in its activities.

One may wonder whether the EFSA has sufficient powers in these areas. It has, for example, only an advisory role in crisis management. It has more independent powers with regard to risk communication. These independent powers are tempered, as it has to act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.<sup>109</sup> It may be questioned whether the Authority will be able to carry out this task independently. It should therefore be considered whether more powers of risk management should be delegated to the EFSA, combined with more political control.

It is clear that an interdisciplinary approach should be adopted to tackle all these and other issues. For lawyers, this implies the task of developing or redesigning the institutional structures, thus, giving form to innovative approaches to food safety, and risk more generally. One of the up-coming challenges will be to apply general principles and new instruments of governance to both risk assessment and risk management. In this lecture, I have tried to give you examples of some such challenges.

To come back to our first questions: it is still safe to eat farmed salmon? Should we believe the American or the European scientists? I have tried to show you the complexities that are involved in answering these questions. Much will depend on the confidence we have in our European food safety authorities. The credibility of these authorities, in turn, will depend, in part, on the level of transparency of their activities, to what extent they involve the stakeholders in their activities and the way in which they communicate the process and results of such activities to the general public.

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<sup>108</sup> D. Chalmers, *supra* note 55, p. 549.

<sup>109</sup> Article 40(3) of Regulation (EC) No 178/2002, *supra* note 64.

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